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EXAMINER

CROW, ROBERT THOMAS

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,786

Applicant(s)

OLDHAM ET AL.

Examiner

Robert T. Crow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,15-21 and 81-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10,15-21 and 81-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 8 September 2006 in which claims 1 and 4-8 were amended, claims 2, 3, 11-14, and 22-60 were canceled, and new claims 81-87 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1, 4-10, 15-21, and 81-87 are under prosecution.

Information Disclosure Statement

2. The Information Disclosure Statement filed 6 October 2006 is acknowledged. The International Search Report has been considered but has been lined through because there is no publication date. See 37 CFR 1.98.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 86-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 86-87 are indefinite in claim 86, which recited the limitation "a top surface, and an input channel" in line 5 of claim 86. The comma after the word "surface" makes it unclear if the input channel is an integral part of the lid plate or if the input channel is a structure that is separate from the lid plate. It is suggested the claim be amended to clarify the positioning of the input channel relative to the other parts of the device.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4-6, 8-9, 15, 17, 82, and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002).

Regarding claim 1, Unger et al teach a microfluidic device. In a single exemplary embodiment, Unger et al teach the device illustrated in Figure 52C, which shows a sample-containment region plate; namely, elastomeric portion 5604 comprising bridge 5614. Bridge 5614 is the sample containment region formed in plate 5604 and is part of fluid channel 5606 (paragraph 0422). Biopolymer synthesis is carried out in the channels (paragraph 0292); therefore, bridge 5614 is a sample containment region capable of containing a sample within the sample containment plate. Unger et al teach the device further comprises a lid plate disposed on the sample containment region plate; namely, elastomeric portion 5600 of Figure 52C. Elastomeric portion 5600 has an outlet opening in the form of the end of channel 5606, which is in fluid communication with sample containment region 5614 and extends through lid plate 5600 to the top surface (paragraph 0422), wherein the top surface is the surface of elastomeric portion 5600 opposite from

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elastomeric portion 5606 and shown juxtaposed with the open un-numbered block at the bottom of Figure 52C.

The device of Unger et al also comprises at least one non-porous, gas-permeable sealing plug disposed in an plugging the outlet opening; namely, gas-permeable elastomers plug all but one of the channel entries of the device (paragraph 0450). Unger et al also teach the non-porous, gas-permeable plugs are polysiloxane materials (paragraphs 0191-0191).

Regarding claims 4-6, Unger et al teach the device of claim 1, wherein the non-porous, gas permeable material comprises a polydialkylsiloxane material; namely, the elastomeric materials comprise polydimethylsiloxane (paragraphs 0190 and 0191).

Regarding claim 8, Unger et al teach the device of claim 1, wherein a channel is provided between the outlet opening and the sample containment region; namely, channel 5610 connects containment region 5614 and outlet opening 5606 (Figure 52C and paragraph 0422). Unger et al also teach the channels have control lines that function as micro-valves (paragraph 0010).

Regarding claim 9, Unger et al teach the device of claim 8, wherein the valve is in a closed state and the fluid communication through the channel is interrupted; namely, the valves close to seal the channel (paragraph 0016).

Regarding claim 15, Unger et al teach the device of claim 1, wherein the at least one sample-containment region contains a sample therein; namely, biopolymer synthesis is carried out in the channels (paragraph 0292).

Regarding claim 17, Unger et al teach the device of claim 1, wherein the sample containment region further comprises a nucleic acid probe; namely, nucleic acid synthesis is carried out in the channels (paragraph 0292).

Regarding claim 82, Unger et al teach the device of claim 1, further comprising a substrate support disposed on a bottom surface of the sample containment region plate; namely, non-channel bearing faces are placed into contact and sandwiched between two substrates (paragraph 0096).

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Regarding claim 84, Unger et al teach the device of claim 82, wherein the substrate support comprises a polysiloxane material; namely, the substrates are elastomers (paragraph 0127), wherein the elastomers comprise polydimethylsiloxane (paragraphs 0190 and 0191).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) in view of Dvornic et al (U.S. Patent Application Publication No. US 2003/0088024 A1, issued 8 May 2003).

Regarding claim 7, Unger et al teach the microfluidic device of claim 1. In a single exemplary embodiment, Unger et al teach the device illustrated in Figure 52C, which shows a sample-containment region plate; namely, elastomeric portion 5604 comprising bridge 5614. Bridge 5614 is the sample containment region formed in plate 5604 and is part of fluid channel 5606 (paragraph 0422). Biopolymer

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synthesis is carried out in the channels (paragraph 0292); therefore, bridge 5614 is a sample containment region capable of containing a sample within the sample containment plate. Unger et al teach the device further comprises a lid plate disposed on the sample containment region plate; namely, elastomeric portion 5600 of Figure 52C. Elastomeric portion 5600 has an outlet opening in the form of the end of channel 5606, which is in fluid communication with sample containment region 5614 and extends through lid plate 5600 to the top surface (paragraph 0422), wherein the top surface is the surface of elastomeric portion 5600 opposite from elastomeric portion 5606 and shown juxtaposed with the open un-numbered block at the bottom of Figure 52C.

The device of Unger et al also comprises at least one non-porous, gas-permeable sealing plug disposed in an plugging the outlet opening; namely, gas-permeable elastomers plug all but one of the channel entries of the device (paragraph 0450). Unger et al also teach the non-porous, gas-permeable plugs are polysiloxane materials (paragraphs 0191-0191).

While Unger et al teach the crosslinking of polysiloxanes (paragraph 0174), Unger et al are silent with respect to weight percents.

However, Dvornic et al teach crosslinked hyperbranched polysiloxanes comprising the reaction product of an uncrosslinked reactive polysiloxane monomer. In the single exemplary embodiment of Example 1, Dvornic et al teach 45.83 g of tetrakis (dimethylsiloxy)silane and about 0.01 to about 50 percent by weight of a polysiloxane crosslinker (e.g., 30 g of 1,3-divinyltetraethoxydisiloxane) with the added advantage that the polymers allow for the attachment of a variety of molecules (paragraph 0005).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the crosslinked polysiloxane device as taught by Unger et al with the crosslinked polysiloxane polymers as taught by Dvornic et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in polymers that allow for the attachment of a variety of molecules as explicitly taught by Dvornic et al (paragraph 0005).

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10. Claims 1, 10, 19-21, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) in view of Anderson et al (Anal. Chem., vol. 72, pages 3158-3164, (15 July 2000)).

Regarding claims 10, 19, and 81, Unger et al teach the microfluidic device of claim 1. In a single exemplary embodiment, Unger et al teach the device illustrated in Figure 52C, which shows a sample-containment region plate; namely, elastomeric portion 5604 comprising bridge 5614. Bridge 5614 is the sample containment region formed in plate 5604 and is part of fluid channel 5606 (paragraph 0422). Biopolymer synthesis is carried out in the channels (paragraph 0292); therefore, bridge 5614 is a sample containment region capable of containing a sample within the sample containment plate. Unger et al teach the device further comprises a lid plate disposed on the sample containment region plate; namely, elastomeric portion 5600 of Figure 52C. Elastomeric portion 5600 has an outlet opening in the form of the end of channel 5606, which is in fluid communication with sample containment region 5614 and extends through lid plate 5600 to the top surface (paragraph 0422), wherein the top surface is the surface of elastomeric portion 5600 opposite from elastomeric portion 5606 and shown juxtaposed with the open un-numbered block at the bottom of Figure 52C.

The device of Unger et al also comprises at least one non-porous, gas-permeable sealing plug disposed in an plugging the outlet opening; namely, gas-permeable elastomers plug all but one of the channel entries of the device (paragraph 0450). Unger et al also teach the non-porous, gas-permeable plugs are polysiloxane materials (paragraphs 0191-0191).

Unger et al teach the device comprises a plurality of channels (paragraph 0020) and chambers (paragraph 0279), which are interpreted as being synonymous because both channels and chambers (i.e., reservoirs) are used for performing biopolymer synthesis reactions (paragraph 0292). While Unger et al teach the bridging structure of Figure 52C, which is the sample-containment region formed in the sample

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containment region plate of instant claim 1, Unger et al do not specifically teach a plurality of the bridging structures of Figure 52C (i.e., a plurality of sample-containment regions) formed in the plate.

However, Anderson et al teach a plurality of bridging channel structures in a microfluidic device; namely, the coiled channel crossings of Figure 5. The plurality of channel crossings are part of a device fabricated from polydimethylsiloxane using a sample containment region plate and a lid plate (i.e., two masters; caption of Figure 5) and the plurality of channel crossings has the added advantage of providing a structure that dissipates heat effectively and acts as a device for sorting and binning samples (i.e., particles; page 3161, column 2, last paragraph).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device comprising the sample containment regions as taught by Unger et al with the plurality of regions as taught by Anderson et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a structure that dissipates heat effectively and acts as a device for sorting and binning samples as explicitly taught by Anderson et al (page 3161, column 2, last paragraph).

Regarding claim 20, the device of claim 19 is discussed above. Unger et al also teach a plurality of regions containing nucleic acid probes; namely, the device comprises a plurality of channels where solid phase synthesis of nucleic acids is performed (paragraphs 0292-0293 and Figure 32).

Regarding claim 21, the device of claim 19 is discussed above. Unger et al also teach a selected plurality of the regions contain a nucleic acid probe; namely, the device comprises a plurality of channels where solid phase synthesis of nucleic acids is performed in one or more of the plurality of channels (paragraphs 0292-0293 and Figure 32).

11. Claims 1, 16-18, and 82-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) in view of Gong et al (U.S. Patent Application Publication No. US 2003/0138941, published 24 July 2003).

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Regarding claims 16 and 18, Unger et al teach the microfluidic device of claim 1. In a single exemplary embodiment, Unger et al teach the device illustrated in Figure 52C, which shows a sample-containment region plate; namely, elastomeric portion 5604 comprising bridge 5614. Bridge 5614 is the sample containment region formed in plate 5604 and is part of fluid channel 5606 (paragraph 0422). Biopolymer synthesis is carried out in the channels (paragraph 0292); therefore, bridge 5614 is a sample containment region capable of containing a sample within the sample containment plate. Unger et al teach the device further comprises a lid plate disposed on the sample containment region plate; namely, elastomeric portion 5600 of Figure 52C. Elastomeric portion 5600 has an outlet opening in the form of the end of channel 5606, which is in fluid communication with sample containment region 5614 and extends through lid plate 5600 to the top surface (paragraph 0422), wherein the top surface is the surface of elastomeric portion 5600 opposite from elastomeric portion 5606 and shown juxtaposed with the open un-numbered block at the bottom of Figure 52C.

The device of Unger et al also comprises at least one non-porous, gas-permeable sealing plug disposed in an plugging the outlet opening; namely, gas-permeable elastomers plug all but one of the channel entries of the device (paragraph 0450). Unger et al also teach the non-porous, gas-permeable plugs are polysiloxane materials (paragraphs 0191-0191).

Unger et al also teach the device of claim 17, wherein the sample containment region further comprises a nucleic acid probe (e.g., the device has an array of DNA probes; paragraph 0402). Unger et al are silent with respect to dried samples.

However, Gong et al teach a device comprising assay stations (Abstract), which are channels and reaction chambers, having dried nucleic acid primers deposited therein (paragraph 0074) with the added advantage that the dried samples allow pre-application of the samples to the chamber (paragraph 0075).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al with the dried samples as taught Gong et al with a reasonable expectation of success. The ordinary artisan would have been

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motivated to make such a modification because said modification would have resulted in allowing pre-application of the samples to the chamber as explicitly taught by Gong et al (paragraph 0075).

Regarding claim 83, the device of claim 1 is discussed above. Unger et al also teach the device of claim 82, which further comprises a substrate support disposed on a bottom surface of the sample containment region plate; namely, non-channel bearing faces are placed into contact and sandwiched between two substrates (paragraph 0096). Unger et al do not teach a plurality of sample containment regions or a plurality of pads.

However, Gong et al teach a device comprising a lid plate (i.e., a lid) and plurality of sample preparation chambers (paragraph 0053), which are sample containment regions. Gong et al further teach the chambers have sintered glass blocks sealing the lower surface of the chambers (paragraph 0095), which are pads disposed in and sealing the chambers. Gong et al teach the sealed chambers have the added advantage of allowing sample extraction removal of washing buffers through the seals (paragraph 0079).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al with the plurality of sealed chambers as taught Gong et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing sample extraction removal of washing buffers through the seals as explicitly taught by Gong et al (paragraph 0079).

12. Claims 1, 82, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) in view of Levin et al (U.S. Patent No. 6,303,389 B1, issued 16 October 2001).

Regarding claim 85, Unger et al teach the microfluidic device of claim 1. In a single exemplary embodiment, Unger et al teach the device illustrated in Figure 52C, which shows a sample-containment

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region plate; namely, elastomeric portion 5604 comprising bridge 5614. Bridge 5614 is the sample containment region formed in plate 5604 and is part of fluid channel 5606 (paragraph 0422). Biopolymer synthesis is carried out in the channels (paragraph 0292); therefore, bridge 5614 is a sample containment region capable of containing a sample within the sample containment plate. Unger et al teach the device further comprises a lid plate disposed on the sample containment region plate; namely, elastomeric portion 5600 of Figure 52C. Elastomeric portion 5600 has an outlet opening in the form of the end of channel 5606, which is in fluid communication with sample containment region 5614 and extends through lid plate 5600 to the top surface (paragraph 0422), wherein the top surface is the surface of elastomeric portion 5600 opposite from elastomeric portion 5606 and shown juxtaposed with the open un-numbered block at the bottom of Figure 52C.

The device of Unger et al also comprises at least one non-porous, gas-permeable sealing plug disposed in an plugging the outlet opening; namely, gas-permeable elastomers plug all but one of the channel entries of the device (paragraph 0450). Unger et al also teach the non-porous, gas-permeable plugs are polysiloxane materials (paragraphs 0191-0191).

Unger et al also teach the device of claim 82, which further comprises a substrate support disposed on a bottom surface of the sample containment region plate; namely, non-channel bearing faces are placed into contact and sandwiched between two substrates (paragraph 0096). Unger et al do not teach the support and the sample-containment region are hinged together.

However, Levin et al teach sassy cassettes for flow-through binding assays (Abstract); namely, Figure 9, which shows the device having a hinge connecting the upper (i.e., top) plate 102 to the assay cassette 10 (i.e., the sample containment plate) and lower plate 104, which is a support. Levin et al also teach the hinged device has the added advantage of allowing access for delivery of the sample to the chamber (column 3, lines 25-55).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al with the hinge as taught

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Levin et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing access for delivery of the sample to the chamber as explicitly taught by Levin et al (column 3, lines 25-55).

13. Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al (U.S. Patent Application Publication No. US 2003/0138941, published 24 July 2003) in view of Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002).

Regarding claim 86, Gong et al teach a microfluidic device. In a single exemplary embodiment, Gong et al teach the device of Figure 4, which has substrate 36, which is a through-hole plate. Gong et al also teach the substrate has a plurality of sample chambers 6 (paragraph 0053), which are holes that extend all the way through the top surface and the bottom surface of substrate 36. Gong et al further teach the device has a sealing layer 40 of Figure 4 (paragraph 0083), which is a lid. Gong et al teach channel 5 comprising inlet 2 of Figures 3-4, which extends from inlet 2 to sample chamber 6 (paragraph 0095), and fluidically connects the sample preparation chambers to the inlet (paragraph 0053) through sealing lid layer 40 (Figure 4).

Gong et al teach the device has at least one non-porous, gas-permeable sealing plug disposed in a channel; namely, sealing layer 40 is gas permeable (paragraph 0098) and further comprises valves (paragraph 0083) provided in any channel (i.e., channel 5; paragraph 0085). Sealing layer 40 consists of the elastomer polydimethylsiloxane (paragraph 0082); therefore, the valve is a non-porous, gas-permeable sealing plug disposed in and plugging the outlet opening. Gong et al also teach absorbent material containing channel 5 disposed on the bottom surface of the through-hole plate 36 (Figure 4 and paragraph 0097). While the channel is outside of plate 36, Gong et al do not explicitly teach a substrate support disposed on the bottom surface of the through-hole plate.

However, Unger et al teach a microfluidic device comprising a hole plate; namely, elastomeric portion 5604 comprising bridge 5614, which is part of fluid channel 5606 (paragraph 0422). Unger et al

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teach the device further comprises a lid plate disposed on the sample containment region plate; namely, elastomeric portion 5600 of Figure 52C. Elastomeric portion 5600 has an outlet opening in the form of the end of channel 5606, which is in fluid communication with the hole plate and extends through lid plate 5600 to the top surface (paragraph 0422). The device of Unger et al also comprises at least one non-porous, gas-permeable sealing plug disposed in an plugging the outlet opening; namely, gas-permeable elastomers plug all but one of the channel entries of the device (paragraph 0450). Unger et al also teach the non-porous, gas-permeable plugs are polysiloxane materials (paragraphs 0191-0191). Unger et al additionally teach a substrate support disposed on a bottom surface of the hole plate; namely, non-channel bearing faces are placed into contact and sandwiched between two substrates with the added advantage of producing channels that cross over each other (Figure 51 and paragraph 0421), which allows accurate mixing of solutions at specified relative concentrations (paragraph 0460).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Gong et al with the substrate as taught Unger et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in producing channels that cross over each other, which allows accurate mixing of solutions at specified relative concentrations, as explicitly taught by Unger et al (Figure 51, paragraph 0421, and paragraph 0460).

14. Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al (U.S. Patent Application Publication No. US 2003/0138941, published 24 July 2003) in view of Unger et al (U.S. Patent Application Publication No. US 2002/0029814 A1, published 14 March 2002) as applied to claim 86 above, and further in view of Levin et al (U.S. Patent NO. 6,303,389 B1, issued 16 October 2001).

Regarding claim 87, the device of claim 86 is discussed on pages 12-13 above. Neither Gong et al nor Unger et al teach the support and the sample-containment region are hinged together.

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However, Levin et al teach sassy cassettes for flow-through binding assays (Abstract); namely, Figure 9, which shows the device having a hinge connecting the upper (i.e., top) plate 102 to the assay cassette 10 (i.e., the sample containment plate) and lower plate 104, which is a support. Levin et al also teach the hinged device has the added advantage of allowing access for delivery of the sample to the chamber (column 3, lines 25-55).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the device as taught by Unger et al in view of Gong et al with the hinge as taught Levin et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing access for delivery of the sample to the chamber as explicitly taught by Levin et al (column 3, lines 25-55).

Response to Arguments

15. Applicant's arguments filed 8 September 2006 (i.e., the "Remarks") have been fully considered but they are not persuasive for the reason(s) listed below.

A. Applicant argues on pages 13-14 of the Remarks that Unger et al does not teach or suggest a device having a lid plate comprising an outlet opening and a sample containment region plate, nor do Unger et al teach a sealing plug disposed in and plugging an outlet opening.

However, Unger et al teaches a device comprising a sample-containment region plate; namely, elastomeric portion 5604 comprising bridge 5614, which is part of fluid channel 5606 (paragraph 0422). Unger et al teach the device further comprises a lid plate disposed on the sample containment region plate; namely, elastomeric portion 5600 of Figure 52C. Elastomeric portion 5600 has an outlet opening in the form of the end of channel 5606, which is in fluid communication with sample containment region 5614 and extends through lid plate 5600 to the top surface (paragraph 0422).

The device of Unger et al also comprises at least one non-porous, gas-permeable sealing plug disposed in an plugging the outlet opening; namely, gas-permeable elastomers plug all but one of the

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channel entries of the device (paragraph 0450). Unger et al also teach the non-porous, gas-permeable plugs are polysiloxane materials (paragraphs 0191-0191). Thus, Unger et al teaches each and every element of claim 1, and therefore anticipates claim 1.

B. Applicant's remaining arguments on pages 14-17 of the Remarks have been considered but are moot in view of the amendments, withdrawn rejections, and new grounds for rejection necessitated by the amendments.

Conclusion

16. No claim is allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Robert T. Crow
Examiner
Art Unit 1634



JULIET C. SWITZER
PRIMARY EXAMINER